

REMARKS/ARGUMENT

Claims 25, 28-32, and 34-37 are pending before amendments. Claim 1-24, 26, 27 and 33 have been cancelled. Claims 36 and 37 are withdrawn.

Claims 36 and 37 are withdrawn as being drawn to a non-elected invention through constructive election.

Claim Rejections - under 35 U.S.C. §103

Claims 25, 28-32, 34 and 35 have been rejected under 35 USC § 103(a) as being unpatentable over Hunter *et al.* U.S. Patent No. 5,886,026 in view of Wang (U.S. Patent No. 6,379,379). Applicants traverse.

In order to establish a *prima facie* case of obviousness, the Examiner must (1) provide an explicit, cogent reason based on the foregoing why it would be obvious to modify the prior art to arrive at the claimed invention; (2) there must be a reasonable expectation of success; and (3) the prior art references must teach or suggest all the claim limitations. The Examiner has failed in several of these elements.

No Rational Reason

Claim 25 requires “polymeric particles containing a therapeutic substance embedded within the coating layer, wherein the coating layer comprises a polymer different than the polymer from which the particles are made, wherein the coating layer is free from any therapeutic substances.” As the Examiner admits on page 5 of the Final Office Action dated May 22, 2009, “Hunter does not [teach or suggest] that their coating layer is *free from* any therapeutic substances.” Independent claim 32 also has a similar limitation.

In order to cure the deficiency of Hunter, the Examiner cites Wang. However, the Examiner fails to give a rational reason as to why one would incorporated an encapsulated drug of Hunter in the multi-layer structure of Wang, and also why there would be an expectation of success without undue experimentation.

The Examiner’s reason for combining the particles of Hunter into the multi-layers of Wang is because “[t]he expected result would be an enhanced stent for beneficial treatment of

restenosis.” This is a conclusory statement, nothing more. “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418, (2007). The Examiner gives no reason as to how the stents of Hunter or Wang would be enhanced. The Examiner has not articulated how removal of the drug from the hunter layer would enhance Hunter’s efficacy. Alternatively, the Examiner has failed to articulate how adding particles of Hunter to the Wang stent would enhance Wang’s efficacy, mostly considering Wang teaches that at least one layer having a drug must be used.

Applicants have identified the problem to solve and a solution to the problem as stated in the prior Amendment filed February 10, 2009. Having a coating layer that is free from any therapeutic substances is important because it allows for greater control of the release of the loaded microparticles containing the therapeutic substance. The use of microparticles allows for higher drug-loading at a particular target site. In addition, in the past, “drug release rates may also be inadequate since the rate at which the drug is released or delivered to the target site is a function of the chemical and/or biological properties of the polymer in which the drug is embedded.” (See specification, page 2, lines 25-28). Hunter and Wang have both utterly failed to recognize any of these problems. In fact, they both emphatically practice the very problem which the present invention aims to cure - - namely, both Hunter and Wang add their drugs to the layers. Even though Wang does have a drug free layer, Wang mandates the use of a drug within at least one of the layers.

Obvious To Try Argument

Even if the Examiner’s reason for combining Hunter and Wang were rational, there are so many combinations of layers containing polymers and drugs presented by Wang that one of skill in the art would not have an expectation of success without undue experimentation. **The Examiner is essentially making an “Obvious to Try” argument, which is not permissible.**

MPEP § 2145 (X)(B) states that “An ‘obvious to try’ rationale may support a conclusion that a claim would have been obvious where one skilled in the art is choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success. [A] person

of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely that product [was] not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *KSR*, 550 U.S. 398, 421, 82 USPQ2d 1385, 1397 (2007).

Wang merely teaches that "[s]ince there are many drugs and many polymers, the stent can have multiple layers of different polymers with the same or different drugs." (Col. 6, lines 24-26). This passage, along with the rest of the Wang disclosure does not demonstrate "a finite number of identified, predictable solutions, with a reasonable expectation of success."

Further, no specific variables are identified as critical, and how to determine which layer has what drug or which layer doesn't have a drug is not disclosed.

MPEP § 2145 (X)(B), quoting *O'Farrell*, states:

The admonition that 'obvious to try' is not the standard under § 103 has been directed mainly at two kinds of error. In some cases, what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, **where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful...** In others, what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where **the prior art gave only general guidance** as to the particular form of the claimed invention or how to achieve it. *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (emphasis added).

There are many drug, polymer, and drug-polymer layer combinations taught by Wang and no direction as to which of the choices are likely to be successful. At least 45 different types of polymers/coatings are given in column 4, lines 7-31. Wang merely gives general guidance at best. Thus, there is no reasonable expectation of success based on the teachings of Wang to modify the particles of Hunter to arrive at independent claims 25 or 32 of the present invention.

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Therefore, claim 25 is not obvious over Hunter in view of Wang. Additionally, claims 28-31 depend from claim 25 and are not obvious for the reasons above. Similarly, claim 35 depends from independent claim 32, which is not obvious in view of Hunter and Wang. Accordingly, dependent claim 35 is not obvious over Hunter in view of Wang.

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Conclusion

In light of the foregoing claim amendments and remarks, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

Respectfully submitted,

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